

12/02/02

FORM APPROVED  
OMB NO. 0579-XXXX  
OMB NO. 0920-XXXX  
EXP DATE XXXX/XXXX



## GUIDANCE DOCUMENT FOR REPORT OF TRANSFER OF SELECT BIOLOGICAL AGENTS AND TOXINS



### INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select biological agents and toxins have been published by HHS (42 CFR 73; December 9, 2002) and by USDA (9 CFR 121 and 7 CFR 331; December 9, 2002).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities or facilities in complying with this legal obligation.

A registered entity or facility is required by law (42 CFR 73.14, 9 CFR 121 and 7 CFR 331) to file this form with either CDC or APHIS when they wish to transfer a select biological agent or toxin. The agency that the Responsible Official (RO) should contact is determined by the type of select biological agent or toxin involved in the transfer. For HHS agents, the RO should contact CDC by facsimile (404-498-2265). For USDA agents, the RO should contact APHIS (for animal agents and toxins, telephone: 301-734-3277; facsimile: 301-734-3652). For HHS/USDA overlap agents, the RO should contact either APHIS or CDC. For plant agents and toxins the RO should contact APHIS (telephone: 301-734-5519; facsimile: 301-734-8700). A listing of HHS select biological agents and toxins is available at <http://www.cdc.gov>. A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>. A copy of the form must be kept by the RO for three years.

### INSTRUCTIONS

The purpose of this form is to provide a method for the documentation of the transfer of a select agent. The form must be completed for each transfer of select agents.

#### *Prior to transferring a select agent*

The intended recipient's RO fills out blocks 1 and 2 of the form and submits it to the sender. The sender's RO fills out block 3 and transmits the form via facsimile to CDC (FAX: 404-498-2265) or APHIS (for animal agents and toxins send FAX to 301-734-3652; for plant agents and toxins send FAX to 301-734-8700), as appropriate. CDC or APHIS will then FAX the form back to the sender with an approval confirmation number after verification of the information on the form. If the sender has a suspicion that the agent may not be used for the requested purpose, or there are any other concerns, then the sender should consult with CDC or APHIS prior to the transfer.

#### *Transfer:*

(a) Shipment of the select biological agent or toxin to the recipient. The sender should ship the material to the receiver only after the sender has received a verification number from CDC or APHIS regarding the information in blocks 1 and 2 of the form. The sender completes Block 3 and the shipping information in Block 4, including the date the agent was shipped. Select biological agents and toxins must be packaged, labeled, and shipped in accordance with all federal regulations (e.g., 42 CFR 72, 49 CFR 100-180, 9 CFR 121, and 7 CFR 331) and international (IATA) regulations. It is highly recommended that the sender utilize a method for tracking the movement of the select biological agents and toxins being shipped. Return receipt is required by law for some select biological agents and toxins listed in 42 CFR 72.3(f) and 9 CFR 121.

(b) Transmittal of the form to the CDC or APHIS. The RO from the recipient's entity/facility must fill out Block 4 of the form with the date received and FAX or mail the form to both the Sender's RO and the CDC or APHIS within 2 business days of receipt.

(c) Destruction or depletion of a select agent. The RO of the recipient's entity/facility should complete appropriate table columns of Block 4 of the form within 5 business days that the select agent is depleted or destroyed. A mailed or faxed copy of the form must be sent to the CDC or APHIS.

### OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-3277.



## REPORT OF TRANSFER OF SELECT BIOLOGICAL AGENTS AND TOXINS



### INSTRUCTIONS FOR COMPLETING THIS FORM

**1. RECIPIENT:** Complete blocks 1 and 2 and forward to Sender.

**2. SENDER:** Fill out block 3 and FAX the form to CDC or APHIS to receive confirmation that the recipient is registered to receive requested material. CDC or APHIS will then FAX the form, if approved, to the Sender with a CDC or APHIS confirmation number. Sender should then complete block 4, except for date shipment received and send this form with the shipment to the Recipient.

**3. RECIPIENT:** Complete date received in Block 4. FAX or mail a copy of this form to the sender and to either CDC\* or APHIS\*\*.

**4. WHEN THE SELECT AGENT IS DEPLETED OR DESTROYED:** The RO of the recipient's entity/facility should complete appropriate table columns of Block 4 of this form within 5 business days of the select agent being depleted or destroyed. A mailed copy or faxed copy of the form must be sent to the CDC or APHIS.

\*CDC: Select Agent Program, Mailstop E-79, 1600 Clifton Rd NE, Atlanta, GA 30333; FAX: (404) 498-2265.

\*\*APHIS: For animal agents/toxins: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; FAX: (301) 734-3277. For plant agents/toxins: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; FAX: (301) 734-8700.

### 1 – RECIPIENT (REQUESTOR) INFORMATION

Entity/facility name		Entity/facility registration #		
Recipient name registered with CDC (principle investigator/lab supervisor) Print: _____ Signature: _____		Date	Phone	FAX
Principle investigator (principle investigator/lab supervisor if different from line above) Print: _____ Signature: _____		Date	Phone	FAX
Responsible Official name Print: _____ Signature: _____	Individual I.D. number	Date	Phone	FAX

### 2 – SELECT AGENT DESCRIPTION

Check box as appropriate (only one box per agent or toxin):	
<input type="checkbox"/> Organism: _____ Strain: _____	
<input type="checkbox"/> Select Agent toxin: _____ Type: _____	
<input type="checkbox"/> Recombinant organisms/molecules: _____ Strain: _____	
Characterization information (e.g., strain, GenBank Accession Number, publication citation with additional molecular characterization data, etc.; provide additional information on attached sheet, if needed): _____ _____	
Proposed Use: <input type="checkbox"/> Research <input type="checkbox"/> Diagnostics <input type="checkbox"/> Production <input type="checkbox"/> Other (explain): _____	

### 3 – SENDER (TRANSFEROR) INFORMATION

Entity/facility name		Entity/facility registration #		<input type="checkbox"/> Importation: US PHS or APHIS Permit #	
Sender name registered with CDC (principle investigator/lab supervisor) Print: _____ Signature: _____		Date	Phone	FAX	
Principle investigator (principle investigator/lab supervisor if different from line above) Print: _____ Signature: _____		Date	Phone	FAX	
Responsible Official name Print: _____ Signature: _____	Individual I.D. number	Date	Phone	FAX	

FOR CDC/APHIS USE ONLY	CDC CONFIRMATION NUMBER: _____	DATE: _____	INI: _____
	APHIS CONFIRMATION NUMBER: _____	DATE: _____	INI: _____

4 – SHIPPING INFORMATION		
List each select agent/toxin shipped, including the strain of the agent, if applicable (see example below).		
Number of primary receptacles per outer package _____	Number of outer packages _____	Date agent shipped _____
Carrier waybill (tracking) # _____		
Date agent received _____		

LIST OF SELECT BIOLOGICAL AGENTS AND TOXINS SHIPPED									
	Select agent	Characterization of agent	Number of vials	Form (powder/liquid)	Vol or wt per vial (e.g., ml, mg)	Total quantity	Concentration/vial (e.g., 10 <sup>8</sup> pfu/ml)	Date depleted or destroyed	RO Initials
	<i>Bacillus anthracis</i>	Sterne strain	5	liquid	5 ml	25 ml	10 <sup>8</sup> /ml		
	<i>Bacillus anthracis</i>	Ames strain	25	liquid	1 ml	25 ml	10 <sup>8</sup> /ml		
1									
2									
3									
4									
5									
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7									
8									
9									
10									
11									

Responsible Official name Print: _____	Signature: _____	RO initials _____	Individual I.D. number _____
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**Record keeping requirements:** Both receiving and sending facilities must maintain records of all transfers.

**Penalties:** Knowingly providing false statements on any part of this form or its attachments will subject the offender to fines of up to \$250,000 (\$500,000 for organizations), imprisonment for up to 5 years or both (18 USC Section 1001). Failure to maintain records constitutes a 1 year misdemeanor (42 USC Section 271).

**Public reporting burden:** Public reporting burden of this collection of information is estimated to average 105 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).